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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,293	09/29/2003	Ronan M. Thornton	P1593 US (2650/163)	4109

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
TRUONG, KEVIN THAO	
ART UNIT	**PAPER NUMBER**
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/04/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/674,293	THORNTON ET AL.	
	Examiner	Art Unit	
	Kevin T. Truong	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *26-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 22-25* is/are rejected.

7)☒ Claim(s) *16-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/03;3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, drawn to a method of applying a drug-polymer coating on a stent, classified in class 427, subclass 2.24.

II. Claims 26-41, drawn to a drug-polymer coated stent, classified in class 623, subclass 1.46.

III. Claims 42-60, drawn to a system for treating a vascular condition, classified in class 606, subclass 1.

V. Claims 60-62, drawn to a method of treating a vascular condition, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II-V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus or by hand that would not necessary required Groups II.

3. Inventions II and III-V are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a materially different product or (2) that the

product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a materially different product such using thread or string or spaying the therapeutic agent on stent.

4. Inventions II and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus such using hooks to hook both ends of the stent while apply coating on the stent.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. During a telephone conversation with Catherine Maresh on 03/29/2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-15 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (U.S. 6,153,252).

As to claims 1 and 22-25, Hossainy et al discloses in figures 1-8; a method of applying a drug-polymer coating on a stent, comprising the steps of: dipping a stent framework (2) into a first polymeric solution, wherein the first polymeric solution

comprises a first polymer, a first therapeutic agent, and a first solvent; drying the first polymeric solution to form a thin drug-polymer layer on the stent framework; dipping the stent framework (2) including the thin drug-polymer layer into a second polymeric solution, wherein the second polymeric solution comprises a second polymer and a second solvent, and wherein the thin drug-polymer layer is insoluble in the second polymeric solution; drying the second polymeric solution to form a thin barrier layer on the first thin drug-polymer layer; and repeating the steps of dipping the stent framework (2) into the first polymeric solution, drying the first polymeric solution, dipping the stent framework (2) into the second polymeric solution, and drying the second polymeric solution until a target drug-polymer coating thickness is disposed on the stent framework (2) (see col. 10, lines 5-31).

As to claims 2-15, Hossainy et al discloses in (col. 3, line 31 thru col. 9, line 62) that wherein the first polymer comprises poly(ethylene-vinyl acetate) with solution between 0.05 percent and 10.0 percent total solids by weight of the first polymer; wherein the first therapeutic agent comprises camptothecin; wherein the first solvent comprises a mixture of chloroform and methanol; wherein the chloroform capable of having concentration between 80 percent and 90 percent; wherein the second polymer comprises one of polyurethane, polycaprolactone, or a blended polymer of polyurethane and polycaprolactone; furthermore, wherein the first polymer of Hossainy et al comprises a rigid thermoplastic polyurethane; the first therapeutic agent comprises 5-fluorouracil; the first solvent comprises a blend of tetrahydrofuran and methanol; the

second polymer comprises an ester-extended polyurethane; and the second solvent comprises chloroform.

Allowable Subject Matter

12. Claims 16-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record disclose or suggest wherein the first polymer comprises a copolymer of methacrylamide, methacrylate and vinyl alcohol; the first therapeutic agent comprises 5-fluorouracil; the first solvent comprises a mixture of chloroform and water; the second polymer comprises a rigid thermoplastic polyurethane; and the second solvent comprises tetrahydrofuran.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Michal et al. (U.S. 6,656,517) and Yan et al (U.S. 6,258,121), both disclose method of coating stent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin T. Truong whose telephone number is 571-272-4705. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin T. Truong
Primary Examiner
Art Unit 3734

ktt